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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,684	10/27/2003	Tetsuya Suga	242791US0CONT	2064
22850	7590	03/08/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			GEORGE, KONATA M	
		ART UNIT	PAPER NUMBER	1616
DATE MAILED: 03/08/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/692,684	SUGA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-51 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-51 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 October 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    - Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/27/03; 8/11/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

Claims 1-51 are pending in this application.

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on April 27, 2001. It is noted, however, that applicant has not filed a certified copy of the Japanese application as required by 35 U.S.C. 119(b).

### ***Drawings***

2. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on October 27, 2003; August 11, 2004 and September 9, 2004 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. In claim 22 it is unclear to the examiner what is meant by "(1)" after the whole sugar. Please examine.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-9, 11-14, 18, 19, 21-24, 26-28, 31, 32, 35, 36, 38, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Kropf et al. (WO 00/54741) as translated by Kropf et al. (US 6,858,214).

Kropf et al. discloses the use of nanoscalar water-soluble  $\beta$ -glucans. The  $\beta$ -glucans are contained in cosmetic and/or pharmaceutical preparation having particle diameters in the range of 10 to 300 nm (equivalent to 0.01 to 0.30  $\mu\text{m}$ ) (col. 1, lines 43-47). Column 1, lines 61-62 disclose a good source for the  $\beta$ -glucans, are yeast, from the *Sacchaomyces* family. Column 2, lines 10-37 disclose a process of producing the particles comprising dissolving the  $\beta$ -glucans under supercritical conditions in a suitable solvent, relaxing the fluid mixture through a nozzle in a vacuum, a gas or liquid, and at the same time evaporating the solvent. To prevent the particles from agglomeration the starting materials should be dissolved in the presence protective colloids or emulsifiers. The composition can further contain adjuvants known in the cosmetic and/or pharmaceutical industry (col. 3, lines 19-34). Column 5, lines 51-52 teach that lecithin can be used in the composition as a hyperfatting agent.

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6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jamas et al. (US 5,741,495).

Jamas et al. disclose a  $\beta$ -glucan drug delivery system (abstract).

7. Claims 1-4, 9, 10, 15-17, 27, 28, 36, 37, 42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al. (JP403099005A).

Kobayashi et al. discloses a cosmetic comprising a mushroom extract. The extract can be obtained by one of two methods, (1) rushed in a raw or dried state to an average particle size of 0.05- 0.5mm (equivalent to 50-500  $\mu\text{m}$ ) or (2) extracted with water, lower alcohol or mixtures thereof.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. The following references were used are prior art under 35 U.S.C. 102(e) as applicant has not provided a certified translated copy of the priority document.

9. Claims 1-9, 11-13, 26-28, 31-33, 36, 40, 42, 45-48 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Ostroff et al. (US 2005/0245480).

Ostroff et al. discloses the use of particulate, bioavailable  $\beta$ -glucan, wherein the particle is a microparticle having a particles size of 1 micron or less (paragraphs [0009-0010]). Paragraph [0017] discloses a method of preparing the  $\beta$ -glucan particles by a

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method of finely grinding yeast cell walls. Paragraph [0036] discloses a process for producing β-glucan particles involving an extraction and purification of the alkali-insoluble β-glucan particles from yeast or fungal membranes. Paragraph [0030] also discusses oral anti-infective and radiochemoprotective activities of β-glucan derived from mushrooms and yeast.

10. Claims 1-3 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Sandewicz et al. (US 6,645,502).

Sandewicz et al. discloses a cosmetic composition containing mushroom extract. The mushroom extract is preferably in a powdered form (col. 2, lines 45-60). Also note example 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 6-9, 26-36-38, 42, 43 and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamas et al. (US 5,741,495).

Jamas et al. disclose a β-glucan drug delivery system (abstract). The β-glucan delivery system of the prior art are particles which are essentially micron-sized (col. 3,

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lines 43-46). Column 3, lines 51-53 teach that the β-glucan is purified from yeast cell walls. Column 3, lines 17-21 teach that the present invention comprises a glucan particle and a drug in combination with a drug delivery vehicle. Column 4, lines 33-55 teaches examples of drugs which can be employed in the particles (i.e. antibiotics, etc.). The prior art does not teach the concentrations of the particles or make up of the composition. The prior art does not teach the composition in the form of a drink.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the composition as a drink. Column 5, lines 57-65 disclose methods of administration such as orally, intramuscularly, etc. It also states that the composition can be formulated into a liquid solution, tablet, etc. Therefore, one could from this disclosure formulate the instant invention into a drink for oral consumption. With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

12. Claims 20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kropf et al. (WO 00/54741) as translated by Kropf et al. (US 6,858,214).

See above for statement of rejection. The prior art does not teach that the emulsifier is lecithin or that the particles form micelles.

It would have been obvious to one of ordinary skill in the art to realize that since both the prior art and claimed invention incorporates lecithin into the composition then it

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would contain both characteristics as an emulsifier and a hyperfatting agent since it is the same compound. With respect to the formation of micelles, it is obvious that they form after the process of making the particles or else it would have been necessary to prevent the particles from agglomeration in the presence protective colloids or emulsifiers (col. 2, lines 23-25).

### ***Conclusion***

13. Claims 1-51 are rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600